



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Gamache

U.S. Serial No. 10/650,006

Filed: August 26, 2003

Examiner: NYA

Group Art Unit: NYA

For: "Methods of Treating Dry Eye
Disorders"

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on this date:

Date

September 15, 2003
Jeannie Burke
Jeannie Burke

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. 1.56

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56. Applicant submits the following patents, articles and other information:

U.S. Patent Application Publication No. 2001/0031260 A1, Lee et al., published October 18, 2001 for "Treatment Method"

U.S. Patent No. 4,131,651, Shah et al., issued December 26, 1978, for "Treatment of Dry Eye"

U.S. Patent No. 4,370,325, Packman, issued January 25, 1983, for "Pharmaceutical Compositions and Method of Treatment"

U.S. Patent No. 4,409,205, Shively, issued October 11, 1983, for "Ophthalmic Solution"

U.S. Patent No. 4,744,980, Holly, issued May 17, 1988, for "Ophthalmic Solution for Treatment of Dry Eye Syndrome"

U.S. Patent No. 4,818,537, Guo et al., issued April 4, 1989, for "Liposome Composition for Treating Dry Eye"

U.S. Patent No. 4,883,658, Holly, issued November 28, 1989, for "Ophthalmic Solution for Treatment of Dry-Eye Syndrome"

U.S. Patent No. 4,914,088, Glonek et al., issued April 3, 1990, for "Dry Eye Treatment Solution and Method"

U.S. Patent No. 4,966,773, Gressel et al., issued October 30, 1990, for "Topical Ophthalmic Compositions Containing Microfine Retinoid Particles"

U.S. Patent No. 5,041,434, Lubkin, issued August 20, 1991, for "Drugs for Topical Application of Sex Steroids in the Treatment of Dry Eye Syndrome, and Methods of Preparation and Application"

U.S. Patent No. 5,075,104, Gressel et al., issued December 24, 1991, for "Ophthalmic Carboxy Vinyl Polymer Gel for Dry Eye Syndrome"

U.S. Patent No. 5,174,988, Mautone et al., issued December 29, 1992, for "Phospholipid Delivery System"

U.S. Patent No. 5,278,151, Korb et al., issued January 11, 1994, for "Dry Eye Treatment Solution"

U.S. Patent No. 5,290,572, MacKeen, issued March 1, 1994, for "Ophthalmic Composition for Treating Dry Eye"

U.S. Patent No. 5,294,607, Glonek et al., issued March 15, 1994, for "Dry Eye Treatment Process and Solution"

U.S. Patent No. 5,371,108, Korb et al., issued December 6, 1994, for "Dry Eye Treatment Process and Solution"

U.S. Patent No. 5,578,586, Glonek et al., issued November 26, 1996, for "Dry Eye Treatment Process and Solution"

U.S. Patent No. 5,696,166, Yanni et al., issued December 9, 1997, for "Compositions Containing Hydroxyecosatetraenoic Acid Derivatives and Methods of Use in Treating Dry Eye Disorders"

U.S. Patent No. 5,800,807, Hu et al., issued September 1, 1998, for "Ophthalmic Compositions Including Glycerin and Propylene Glycol"

U.S. Patent No. 6,083,903, Adams et al., issued July 4, 2000, for "Boronic Ester and Acid Compounds, Synthesis and Uses"

U.S. Patent No. 6,255,343, Belanger, issued July 3, 2001, for "2,2-Difluoro 15-Hydroxyeicosatetraenoic Acid Analogs and Methods of Use"

U.S. Patent No. 6,320,062, Belanger, issued November 20, 2001, for "15-Hydroxyeicosatetraenoic Acid Analogs with Enhanced Metabolic Stability and Methods of Their Use in Treating Dry Eye Disorders"

U.S. Patent No. 6,326,499, Belanger, issued December 4, 2001, for "Omega Chain Modified 15-Hydroxyeicosatetraenoic Acid Derivatives and Methods of Their Use for the Treatment of Dry Eye"

U.S. Patent No. 6,331,566, Conrow et al., issued December 18, 2001, for "Heteroatom-Interrupted Analogs of 15-Hydroxyeicosatetraenoic Acid and Methods of Use"

U.S. Patent No. 6,331,644, Klimko et al., issued December 18, 2001, for "3-Heteroatom Substituted and Two Carbon Homologs of 15-HETE and Methods of Use"

U.S. Patent No. 6,342,525, Klimko et al., issued January 29, 2002, for "Benzenoid Derivatives of 15-Hydroxyeicosatetraenoic Acid and Methods of Their Use in Treating Dry Eye Disorders"

U.S. Patent No. 6,353,012, Hellberg et al., issued March 5, 2002, for "15-Hydroxyeicosatetraenoic Acid-Related Compounds and Methods of Use"

U.S. Patent No. 6,353,022, Schneider et al., issued March 5, 2004, for "Compositions Containing Hydroxyeicosatetraenoic Acid Derivatives and Methods of Use in Treating Dry Eye Disorders"

U.S. Patent No. 6,353,032, Graff et al., issued March 5, 2002, for "Phospholipids of Hydroxyeicosatetraenoic Acid-Like Derivatives and Methods of Use"

U.S. Patent No. 6,399,322, Glimcher et al., issued June 4, 2002, for "Methods and Compositions for Regulating T Cell Subsets by Modulating Transcription Factor Activity"

U.S. Patent No. 6,429,227, Schneider et al., issued August 6, 2002, for "Hydroxyeicosatetraenoate Salts, Compositions and Methods of Use in Treating Dry Eye Disorders"

U.S. Patent No. 6,458,853, Graff et al., issued October 1, 2002, for "Phospholipids of Hydroxyeicosatetraenoic Acid-Like Derivatives and Methods of Use"

U.S. Patent No. 6,458,854, Graff et al., issued October 1, 2002, for "Phospholipids of Hydroxyeicosatetraenoic Acid-Like Derivatives and Methods of Use"

U.S. Patent No. 6,552,084, Klimko et al., issued April 22, 2003, for "Hydroxyeicosatetraenoic Acid Analogs and Methods of Their Use in Treating Dry Eye Disorders"

JP10036289, Kojima et al., issued February 10, 1998, for "Proteasome Inhibitors for Prevention of Nerve Cell Degeneration and Apoptosis"

JP10330257, Manabu et al., published December 15, 1998, for "Inhibitor of Cytokine Production for Ocular Topical Use"

WO 00/03705, Yanni et al., published January 27, 2000, for "Use of 11-(3-Dimethylaminopropylidene)-6,11-Dihydrodibenz(B,E)oxepin-2-acetic Acid for the Manufacture of a Medicament for Treating Non-Allergic Ophthalmic Inflammatory Disorders and for the Prevention of Ocular Neovascularization"

WO 02/13812, Pershadsingh, published February 21, 2002, for "Methods for Treating Inflammatory Diseases"

Lemp et al., "Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes," *CLAO*, Vol. 21(4), pp. 221-231 (1995)

McCulley et al., "Tear Film Structure and Dry Eye," *Contactologia*, Vol. 20, pp. 145-149 (1998)

Marsh et al., "Topical Nonpreserved Methylprednisolone Therapy for Keratoconjunctivitis Sicca in Sjogren Syndrome," *Ophthalmology*, Vol. 106(4), pp. 811-816 (1999)

Pisella et al., "Flow Cytometric Analysis of Conjunctival Epithelium in Ocular Rosacea and Keratoconjunctivitis Sicca," *Ophthalmology*, Vol. 107(10), pp. 1841-1849 (2000)

Shine et al., "Keratoconjunctivitis Sicca Associated with Meibomian Secretion Polar Lipid Abnormality," *Arch. Ophthalmol.* Vol. 116, pp. 849-852 (1998)

Tauber et al., "A Dose-Ranging Clinical Trial to Assess the Safety and Efficacy of Cyclosporine Ophthalmic Emulsion in Patients with

Keratoconjunctivitis Sicca," Lacrimal Gland, Tear Film and Dry Eye Syndromes 2, edited by Sullivan et al., Plenum Press, New York, pp. 969-972 (1998)

The Examiner's attention is brought to the following co-pending applications: 10/150,191; 10/152,142; 10/150,193; 10/150,199; and 10/150,219.

For the convenience of the Examiner, the patents and articles are also listed on PTO Form 1449.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

Applicant requests that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

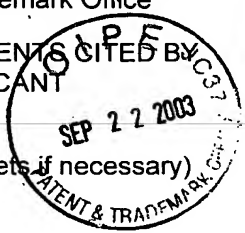
ALCON

Sept. 15, 2003
Date

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(817) 551-3066
Attorney Docket No.: 2427

Form PTO-1449 U.S. Dept. of Commerce Patent & Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		ATTY. DOCKET NO. 2427 APPLICANT Gamache FILING DATE August 26, 2003		SERIAL NO. 10/650,006 GROUP NYA		
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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	2001/0031260	10/18/01	Lee et al.	424	145.1	
	AB	4,131,651	12/26/78	Shah et al.	424	78	
	AC	4,370,325	01/25/83	Packman	424	245	
	AD	4,409,205	10/11/83	Shively	424	78	
	AE	4,744,980	05/17/88	Holly	424	78	
	AF	4,818,537	04/04/89	Guo	424	427	
	AG	4,883,658	11/28/89	Holly	424	80	
	AH	4,914,088	04/03/90	Glonek et al.	514	76	
	AI	4,966,773	10/30/90	Gressel et al.	424	489	
	AJ	5,041,434	08/20/91	Lubkin	514	182	
	AK	5,075,104	12/24/91	Gressel et al.	424	78.04	

FOREIGN PATENT DOCUMENTS								
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
					YES	NO		
AL	JP-10036289	02/10/98	Japan (abstract only)					
AM	JP-10330257	12/15/98	Japan		X			
AN	WO 00/03705	01/27/00	PCT					
AO	WO 02/13812	02/21/02	PCT					
AP								

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Lemp et al., "Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes," <i>CLAO</i> , Vol. 21(4), pp. 221-231 (1995)	
AS	McCulley et al., "Tear Film Structure and Dry Eye," <i>Contactologia</i> , Vol. 20, pp. 145-149 (1998)	
AT	Marsh et al., "Topical Nonpreserved Methylprednisolone Therapy for Keratoconjunctivitis Sicca in Sjogren Syndrome," <i>Ophthalmology</i> , Vol. 106(4), pp. 811-816 (1999)	

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	BA	5,174,988	12/29/92	Mautone et al.	424	45	
	BB	5,278,151	01/11/94	Korb et al.	514	76	
	BC	5,290,572	03/01/94	MacKeen	424	602	
	BD	5,294,607	03/15/94	Glonek et al.	514	76	
	BE	5,371,108	12/06/94	Korb et al.	514	762	
	BL	5,578,586	11/26/96	Glonek et al.	514	76	
	BG	5,696,166	12/09/97	Yanni et al.	514	573	
	BH	5,800,807	09/01/98	Hu et al.	424	78.04	
	BI	6,083,903	07/04/00	Adams et al.	514	2	
	BJ	6,255,343	07/03/01	Belanger	514	552	
	BK	6,320,062	11/20/01	Belanger	552	10	
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	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	BL						
	BM						
	BN						
	BO						
	BP						
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	BR	Pisella et al., "Flow Cytometric Analysis of Conjunctival Epithelium in Ocular Rosacea and Keratoconjunctivitis Sicca," <i>Ophthalmology</i> , Vol. 107(10), pp. 1841-1849 (2000)					
	BS	Shine et al., "Keratoconjunctivitis Sicca Associated with Meibomian Secretion Polar Lipid Abnormality," <i>Arch. Ophthalmol.</i> Vol. 116, pp. 849-852 (1998)					
	BT	Tauber et al., "A Dose-Ranging Clinical Trial to Assess the Safety and Efficacy of Cyclosporine Ophthalmic Emulsion in Patients with Keratoconjunctivitis Sicca," <i>Lacrimal Gland, Tear Film and Dry Eye Syndromes 2</i> , edited by Sullivan et al., Plenum Press, New York, pp. 969-972 (1998)					

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	CA	6,326,499	12/04/01	Belanger	548	252	
	CB	6,331,566	12/18/01	Conrow et al.	514	549	
	CC	6,331,644	12/18/01	Klimko et al.	554	219	
	CD	6,342,525	01/29/02	Klimko et al.	514	532	
	CF	6,353,012	03/05/02	Hellberg et al.	514	381	
	CF	6,353,022	03/05/02	Schneider et al.	514	530	
	CG	6,353,032	03/05/02	Graff et al.	514	912	
	CH	6,399,322	06/04/02	Glimcher et al.	435	29	
	CI	6,429,227	08/06/02	Schneider et al.	514	530	
	CJ	6,458,853	10/01/02	Graff et al.	514	912	
	CK	6,458,854	10/01/02	Graff et al.	514	912	

FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
						YES	NO	
	CL							
	CM							
	CN							
	CO							
	CF							

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	CR	
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	DA	6,552,084	04/22/03	Klimko et al.	514	568	
	DB						
	DC						
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	DL						
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